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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/369,236

08/04/99

KRAFFT

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97002-C

020306 HM22/1002
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EXAMINER

GUPTA, A

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/369,236

Applicant(s)

KRAFFT ET AL.

Examiner

Anish Gupta

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

ELECTION/RESTRICTION

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim 1-14, drawn to non fibrillar amyloid beta oligomeric structure, classified in class 530, subclass 395.
 - II. Claims 15-16, drawn to method or assaying effects of an oligomeric structure by administering the oligomeric structure to the hippocampus and measuring cell body spike, classified in class 436, subclass 86+.
 - III. Claims 17-18, drawn to method of protecting an animal against decrease in learning, classified in class 514, subclass 2.
 - IV. Claims 19-21, drawn to protecting a nerve cell against decreases in long term potentiation, classified in class 436, subclass 86+.
 - V. Claim 22, drawn to method of detecting in a test material binding of oligomeric structure using an antibody, classified in class 436, subclass 547+.
 - VI. Claim 23 and 25, drawn to method of detecting in a test material morphological changes using neuroblastoma cells, classified in class 435, subclass 7.21.
 - VII. Claim 24, drawn to method of detecting in a test material brain cell death using brain slice culture, classified in class 435, subclass 41+.
 - VIII. Claims 26 and 27, drawn to method of detecting in a test material activation of astrocytes using astrocytes, classified in class 435, subclass 4+.
 - IX. Claims 28-29, drawn to method of detecting in a test material long term potentiation in the hippocampus, classified in class 435, subclass 173.1+.
 - X. Claim 30, drawn to method of identifying compounds by comparing portion of viable cells, classified in class 436, subclass 815+.
 - XI. Claims 31-36, drawn to method of identifying compounds using florescence, classified in class 436, subclass 172.

- XII. Claims 37-39, drawn to method of identifying compounds using color changes, classified in class 436, subclass 171.
- XIII. Claim 40, drawn to method of identifying compounds using an assessment of the formation of protein assemblies, classified in class 436, subclass 86+.
- XIV. Claims 41-42, drawn to method of preparing an isolated soluble, globular, non fibrillar amyloid beta oligomeric structure , classified in class 530, subclass 412+.
- XV. Claim 43, drawn to preparing an isolated soluble, globular, non fibrillar amyloid beta oligomeric structure, classified in class 530, subclass 412+.
- XVI. Claim 44, drawn to a method of detecting in a test material and measuring if cell exhibits ADDL-induced aberrant neuronal signal, classified in class 435, subclass 7.21.

2. The inventions are distinct, each from the other because of the following reasons:

All of the methods involving a test material, although use amyloid beta, are distinct in that they involve different method steps and different end results. For example, the method of Group VI involves the morphological changes in neuroblastoma cells. However, this the method of Group VII does not involve the use of neuroblastoma cells nor involves the morphological changes, rather this method involves the measurement of cell death of brain slice cultures. Similarly, the method of Group XI involves the measurement of fluorescence while Group XII involve the measurement of color changes. One method involves the subjecting of the cells to fluorescence while the other does not. Thus all of the methods involving test materials claimed involve, either different test material, i.e. cell, cultures, or subjecting these materials to different stimulus and measure different results.

3. Inventions of Group I and Group II-XIII and XVI related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of claim one can be used in assay method or a treatment method.

Inventions Group I and Group XIV and XV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to

make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of Group I can be directly isolated from an Alzheimer brain.

The two methods of making are distinct in that the methods involve different reagents. For example, the method of Group XIV involves a culture media, whereas the method of Group XV involves the use of alcohol solution. Thus, the methods involve different method steps.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



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